

REMARKS

Applicants have carefully reviewed the Office Action mailed on June 2, 2010, prior to preparing this response. Currently, claim 15 is pending in the application and has been rejected. With this response, claim 15 is amended, and new dependent claims 26-34 are presented. Support for these amendments may be found in the application as originally filed. No new matter is added. Favorable consideration of the above amendments and following remarks is respectfully requested.

Claim Rejections Under 35 U.S.C. §102

Claim 15 is rejected under 35 U.S.C. §102(e) as being anticipated by Wu et al. in U.S. Patent Pub. No. US 2004/0243156 (“Wu”). Applicants respectfully traverse the rejection.

Claim 15 recites “wherein the means for cutting and means for gripping are defined by a series of undulations on the cutting blade in the first fully inflated configuration” and “wherein the undulations curve from side-to-side relative to the longitudinal axis in the first fully inflated configuration” (emphasis added). Applicants assert that Wu does not explicitly, impliedly or inherently disclose these limitations.

Wu shows the wings and blades appearing to have side-to-side undulations when the balloon is in its deflated state. For instance, Wu discloses (last 8 lines of paragraph 0036, emphasis added):

Generally, the use of apparatus 46 results in the alteration of the geometry of balloon 14 so that a generally repeatable deflation shape is formed in the balloon material so that wings 42 are formed and visible when balloon 14 is deflated. It is believed that the disclosed balloon geometry, that may include a plurality of wings 42 having undulations 44, helps render the balloon more foldable, more re-foldable, and more collapsible.

Regarding side-to-side undulations when the balloon is in its fully inflated state, Wu appears to show that the undulations of the wings disappear when the balloon is inflated. Fig. 3 of Wu shows the undulations 44 of the wings 42, when the balloon is deflated, while Fig. 4 of Wu clearly shows an absence of those undulations when the balloon is inflated. Namely, Wu states, “When balloon 14 is inflated, wings 42 may become expanded and, thus, not visible as illustrated in FIG. 4.” Wu, at paragraph 0034.

In Wu, while the undulations of the wings clearly disappear when the balloon is inflated, Wu is silent regarding any undulations of the blades when the balloon is inflated.

In the Applicants' response to the previous Office Action, the Applicants argued that "it is likely that in the inflated state, the cutting members would extend longitudinally along a straight path, without any undulation, as there would be no wings 42, and thus no undulating surface 44 that the cutting members would match". In the present Office Action, the Examiner responds to Applicants' argument, stating that "The cutting members are made of a cutting structure, such as a metallic cutting blade similar to a knife, that has a rigid structure ([0018]). There is no expectation that the undulations in the cutting member will change between first and second configurations because a metallic cutting blade similar to a knife will maintain its shape due to its material composition, which is far different from the material composition of the balloon ([0020])."

Applicants respectfully disagree. Applicants assert that in the Examiner's response to the Applicants' previous argument, the Examiner appears to rely on "expectation" of the rigidity of Wu's blade to conclude that the undulations would remain when the balloon is inflated. Applicants respectfully disagree with this reliance on rigidity. For example, U.S. Pat. Pub. 2005/0228343 to Kelly ("Kelly") describes a cutting balloon catheter and method for mounting a cutting blade on a balloon. Kelly states, "Cutting members 20 may be made from any suitable material such as a metal, metal alloy, polymer, metal-polymer composite, and the like, or any other suitable material." Kelly at paragraph 0013. Kelly describes an arrangement of mounting the cutting blades 20 onto the balloon 16 using a joining member 38 between the cutting blade 20 and the balloon 16. Kelly, at paragraph 0022, states:

In some embodiments, joining member 38 may be formed from a generally flexible or soft material that allows the interface or connection between the cutting member 20 and balloon 16 to be secure while also being, in some embodiments, somewhat elastic or pliable. For example, joining member 38 may be manufactured from a low durometer polyurethane or any other suitable material (including any of the polymers and other materials disclosed herein). Accordingly, cutting member 20 may be securely coupled to balloon 16 while still being able to move laterally about eight degrees or less. Additionally, different portions of cutting member 20 may be able to bend or flex, while other portions remain essentially unchanged. In other embodiments, joining member 38 may be formed from a somewhat harder material.

Thus, Kelly teaches that metal cutting blades, while mounted to the balloon, may be able to bend or flex. Such bending or flexing may facilitate navigating the cutting balloon catheter through the vasculature to a stenosis or lesion.

Applicants further assert that because Wu appears to be silent regarding the undulations of the blades when the balloon is inflated, and because the Examiner appears to rely on blade rigidity to determine if the undulations would disappear or remain when the balloon of Wu is inflated, then it appears that the Examiner is relying on an inherency argument to show that Wu anticipates that the blade undulations remain when the balloon is inflated. Applicants respectfully disagree with this inherency argument.

The MPEP states in Section 2112, subsection IV, paragraph 2:

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

Applicants assert that even though the blade disclosed by Wu may be formed from metal, the blade does not necessarily possess the rigidity to ensure that the undulations of the blade would remain when the balloon is inflated. As taught in Kelly, cutting blades formed of metal may be able to bend and flex while mounted to the balloon. Thus, if constructed as taught in Kelly, the undulations of the cutting blades of Wu in the deflated state may likely disappear in the inflated state such that the cutting members would extend longitudinally along a straight path, without any undulation, as there would be no wings 42, and thus no undulating surface 44 that the cutting members would match. As such, Applicants assert that maintaining the undulations of Wu's blade when the balloon is inflated is not an inherent property of Wu's blade.

As a result, Applicants assert that Wu does not expressly, impliedly or inherently disclose "wherein the means for cutting and means for gripping are defined by a series of undulations on the cutting blade in the first fully inflated configuration" and "wherein the undulations curve from side-to-side relative to the longitudinal axis in the first fully inflated configuration", as recited by claim 15. Applicants assert that claim 15 is not anticipated by Wu. Withdrawal of the rejection is respectfully requested.

Claim 15 is rejected under 35 U.S.C. §102(e) as being anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Shaw et al. in U.S. Patent No. 7,279,002 (“Shaw”). Applicants respectfully traverse the rejection.

Amended claim 15 recites “a metallic cutting blade for severing or breaking up a lesion adhesively bonded to the balloon throughout the entire use of the cutting balloon catheter”.

In contrast, Shaw discloses a cutting blade 104 appearing to have undulations, shown in FIG. 3 as being attached to a stent 100 and not adhesively bonded to a balloon, as recited by claim 15. Shaw discloses (column 4, lines 35-44; emphasis added):

Where the blades 104 are made of a different material than the stent 100, the blades 104 may be affixed to the stent 100 via a suitable means including via the use of adhesives or via welding. For example, where the stent and blades are both made from metal, the blades may be welded to the stent. Where the blades are made of the same material as the stent, the blades may be affixed to the stent using adhesives or welding as described above or may be formed by removing material from a stent preform during manufacture of the stent.

As such, Shaw does not teach or suggest an undulating blade “adhesively bonded to the balloon”, as recited by amended claim 15.

For at least these reasons, Applicants assert that claim 15 is not anticipated by Shaw, and is not obvious in view of Shaw. Withdrawal of the rejection is respectfully requested.

Conclusion

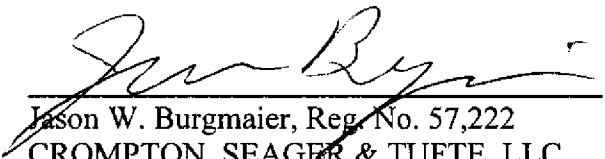
Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Karen M. Cheves et al.

By their Attorney,

Date: June 30, 2010


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